Bartko Pavia

LIFE SCIENCES & HEALTHCARE

OVERVIEW

Bartko Pavia represents clients across the life sciences and healthcare industries, with a focus on regulatory compliance, government enforcement, litigation strategy, and transactional support. Our team understands the complex pressures facing companies bringing innovative therapies, devices, and services to market. We offer targeted legal counsel that helps clients stay compliant, mitigate risk, and respond decisively when regulatory or legal challenges arise.

We work closely with medical device manufacturers, healthcare providers, investors, and consultants to navigate the evolving regulatory landscape—especially where enforcement risk, compliance obligations, and business strategy intersect. Whether advising on post-market obligations, defending against whistleblower actions, or supporting investment decisions with regulatory diligence, Bartko Pavia delivers practical, litigation-ready solutions backed by real-world experience.

We know that in healthcare and life sciences, legal decisions carry business, reputational, and public health consequences. Our mission is to guide clients through those challenges with clarity and confidence.

MEDICAL DEVICE

Bartko Pavia delivers focused legal support to medical device companies navigating complex regulatory frameworks and high-stakes enforcement risk. We work with manufacturers, regulatory consultants, and investors to address compliance obligations, manage crisis events, and prepare for litigation—all with a practical, business-minded approach.

Our strength lies in bridging enforcement insight with real-world operational needs. We counsel clients on everything from Quality System Regulation (QSR) and adverse event reporting to responding to FDA Form 483s, warning letters, and DOJ investigations. When enforcement escalates, we step in with decisive defense strategies—protecting products, reputations, and enterprise value.

Core Focus Areas

- Post-market compliance (QSR, MDR, corrections and removals)
- FDA Form 483s, warning letters, and inspection support
- DOJ/FDA investigations, product seizures, and consent decrees
- False Claims Act (FCA) and Anti-Kickback Statute (AKS) defense
- Regulatory litigation support (including offensive challenges to adverse regulatory decisions and defensive support in products-liability cases)
- Joint litigation support for regulatory consultants
- Product liability defense tied to regulatory risk
- Labeling, marketing, and recall-related litigation exposure
- Litigation-ready compliance audits and crisis management
- Regulatory due diligence for transactions and investments
- Risk mitigation strategy for medtech startups and funders
- Counseling on claim substantiation for advertising and marketing

Bartko Pavia helps device companies not just react—but prepare. Our team delivers compliance strategies with a litigation lens, ensuring that every decision made today stands up to scrutiny tomorrow.

Representative experience

- Represented medical device manufacturer in vaginal mesh litigation
- Managed medical device manufacturer's response to discovery in private antitrust litigation as a third party
- Represented manufacturer in FTC investigation concerning substantiation of advertising claims
- Product liability counsel in "Pain Pump" litigation
- Represented robotic surgery and defibrillator manufacturers in analysis and strategic planning

- Spearheaded multiple successful FDA 483 and Warning Letter remediation projects
- Performed mock FDA and internal quality and regulatory audits

BIOTECHNOLOGY

Bartko Pavia advises biotechnology companies and their investors on how to navigate regulatory complexity and enforcement exposure while advancing scientific and commercial goals. Our work supports early-stage innovators and clinical ventures alike—especially where regulatory risk intersects with litigation, funding, and labeling strategy.

We know biotech clients must think several steps ahead, not just about regulatory approval, but about the legal risks that come with growth and visibility. Our team brings regulatory fluency and enforcement experience to help clients make strong, legally grounded decisions at critical inflection points.

Core Focus Areas

- Risk-aware regulatory counseling throughout development
- Enforcement support tied to marketing or clinical strategy
- False Claims Act (FCA) and Anti-Kickback Statute (AKS) compliance and defense
- Regulatory due diligence for transactions and investments
- Litigation-sensitive labeling and communication strategy
- Product liability risk management for biologics and therapies
- Compliance strategy to support valuation and funding
- Regulatory support in partnership with scientific consultants
- Counseling on claim substantiation for advertising and marketing

Our approach is built for the realities of biotech: high science, high scrutiny, and the need for legal strategies that can scale with innovation.

Representative Experience

- General litigation counsel and resolution of complex and business disputes for early-stage genomic companies, startup biotech, telehealth providers, and new entrance to the healthcare space

- Case and litigation analysis for product liability, IP, trade secret, and breach of contract cases
- Former leading attorney in FTC antitrust investigations and litigation concerning the pharmaceutical and biotechnology industries

HEALTHCARE

Bartko Pavia provides legal guidance to healthcare providers and affiliated organizations facing regulatory scrutiny and evolving business demands. From compliance reviews to fraud investigations, we help clients protect operations, respond to enforcement activity, and implement policies that withstand legal pressure.

Our healthcare practice is rooted in experience with litigation-sensitive compliance—especially in contexts where billing, referrals, and marketing may trigger False Claims Act exposure. We also provide legal support for consultants and business partners who need regulatory backup in complex matters.

Core Focus Areas

- False Claims Act (FCA), Anti-Kickback Statute (AKS), and Sunshine Act compliance and defense
- Defense in qui tam and whistleblower actions
- Internal investigations and disclosure strategies
- Compliance audits designed for enforcement readiness
- Product marketing and communication risk counseling
- Legal partnerships with non-lawyer consultants
- Transactional support with regulatory risk analysis

We offer practical legal strategies that support ongoing compliance while preparing clients to respond confidently to inquiries, audits, and disputes.

Representative Experience

- Lead counsel team in class action antitrust trials for hospital systems in California state and federal courts
- Successfully resolved disputes, litigation, and arbitrations for hospital systems, medical groups, and healthcare clients concerning health plan roll-outs, provider and insurer payment

disputes, breach of contract, and disruptive physicians

- Product liability counsel for major pharmaceutical producers in Class action, MDL, and JPML litigation and subsequent settlement negotiations and claims administration
- Resolution of off-label marketing litigation for major pharmaceutical producers with federal and state enforcers
- MDL and state court antitrust litigation re healthcare insurers
- Counsel for leading US compounding pharmacy
- Privacy litigation concerning data breaches, pixels, and cookies for healthcare providers
- Product liability counsel in “Pain Pump” litigation
- Case and litigation analysis for product liability, IP, trade secret, and breach of contract cases in the life sciences and healthcare industry
- Privacy and antitrust panel counsel for major University and hospital systems
- Led federal investigations and enforcement actions concerning anticompetitive collusive behavior in the health care industry

INSIGHTS

PUBLICATIONS | 06, OCTOBER 2025

MEREDITH VANDERBILT PUBLISHES ARTICLE IN AHLA HEALTH LAW WEEKLY ON FDA DRUG SHORTAGE TRACKING

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